



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/606,592 | 06/26/2003 | Gavril Pasternak | 830002-2001.2 | 8258 |
| 21874 | 7590 | 06/28/2006 | | EXAMINER |
| EDWARDS & ANGELL, LLP | | | | DUTT, ADITI |
| P.O. BOX 55874 | | | | |
| BOSTON, MA 02205 | | | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1649 | |

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/606,592 | PASTERNAK ET AL. | |
| | Examiner | Art Unit | |
| | Aditi Dutt | 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 July 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 81-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 81-94 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 81-84, 88-90, 93-94 drawn to a method of screening compositions for opioid activity in a test cell by measuring the physiologic effect of the composition on the cell, classified in class 435, subclass 375.
 - II. Claims 81, 85-87 and 89-92, drawn to a method of screening composition for opioid binding activity, classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The inventions are independent or distinct; each from the other because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, and goals. In the instant case the different inventions I and II are directed to methods that are distinct both physically and functionally, and are not required one for the other.

Invention I requires the determination of physiological effect of the composition on a test cell, which is not required by the invention of group II. Invention II requires the determination of opioid binding of the compositions, which is not required by the invention of group I. Therefore, a search of both the methods in one patent application would result in an undue burden, since the classification is different, and the subject matter is divergent.

4. Because these inventions are independent or distinct for the reasons given above, have acquired a separate status in the art in view of their different classification and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Species Elections

5. This application contains claims directed to the following patentably distinct species of the claimed inventions I and II.

A) Human KOR-3 splice variant polypeptide

- a) KOR-3A (SEQ ID NO: 6)
- b) KOR-3D (SEQ ID NO: 7)

6. If applicant elects Invention I or II, one species of KOR-3 splice variant polypeptide must also be selected to be considered responsive.

7. Each of the above peptide sequences represents a patentably distinct invention because amino acid sequences and the nucleic acid sequences encoding these proteins are slightly different and require non-coextensive

technical literature searches. Searching both the sequences in a single patent application would provide an undue search burden on the examiner

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 81, 86 and 88 are generic, for example.
9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. **B) Hormone**

- a) Prolactin
- b) Growth Hormone
- c) Gonadotropin-releasing hormone
- d) Adrenocorticotropin
- e) Corticotropin-releasing factor
- f) Luteinizing hormone
- g) Follicle stimulating hormone
- h) Testosterone
- i) Cortisol

13. If applicant elects Invention I, one species of hormone must also be selected to be considered responsive.

14. Each of the above hormone molecules are distinct, having different structure-function relationship, and different regulatory mechanisms from one another and, therefore, represents a patentably distinct invention and would require a separate search of the art that would be burdensome to the examiner.

15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 81 and 83 are generic, for example.
16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1649

19. In response to this requirement, applicants must elect from Groups I-II, and must additionally elect a species of human KOR-3 splice variant polypeptide and hormone for consideration. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).
20. Applicant is reminded that upon the cancellation of claims to a nonelected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Advisory Information

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F 9.00 a.m. to 5.00 p.m. (Eastern standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD

20 June 2006



**BRIDGET BUNNER
PATENT EXAMINER**